

REMARKS

Claims 1-27 are pending in the application and stand rejected. The specification has been amended. In paragraph [0114] the word “agent” was added to “... and the nominal mole ratio of halogenating agent to nicotinamide 4 is about 0.9 to about 1.1.” This correction makes the phrase “halogenating agent” consistent with the other instance of the same phrase in Embodiment VV and in other Embodiments. In paragraph [0117], the word “salt” was made plural as there are several different diazonium salts exemplified in the references which follow this term. In paragraph [0135], “cupric chloride dehydrate” was corrected to “cupric chloride dihydrate”. Basis for this correction is the calculated molecular weight (10.14 g /0.0595 mol = 170 g/mol) corresponding to the molecular formula of CuCl₂·2 H₂O (FW = 170.48 g/mol) and not CuCl₂ (FW = 99.00 g/mol). Applicant respectfully requests reconsideration in view of the Amendments and Remarks herein.

Claims 1-27 were rejected under 35 U.S.C. 112, first paragraph. Applicant respectfully traverses this rejection.

Note is taken of the Examiner’s reference to MPEP §2164.01(a) in support of her conclusion of lack of enablement; however, Applicant respectfully points out MPEP §2164.02 which discusses need for working examples:

The specification need not contain an example if the invention is otherwise disclosed in such manner that one skilled in the art will be able to practice it without an undue amount of experimentation. *In re Borkowski*, 422 F.2d 904, 908, 164 USPQ 642, 645 (CCPA 1970). Lack of a working example, however, is a factor to be considered, especially in a case involving an unpredictable and undeveloped art. **But because only an enabling disclosure is required**, applicant need not describe all actual embodiments. (Emphasis added)

Therefore while an enabling disclosure is required, no working examples are required for an enabling disclosure. The present application provides working Examples 1 – 5 in paragraphs [0130] through [0135] on pages 7 through 9 of the present specification as published (US2007/0161797A1). These Examples illustrate particular embodiments of the invention, but the claims are otherwise well supported by the specification which provides additional embodiments enabling practicing the invention to the fullest extent.

As the Examiner has cited Undue Experimentation Factors c), g) and h) as particularly relevant to the rejection under 35 U.S.C. 112, these factors are addressed below.

Regarding factor c) the Examiner states: “There is no working example of any other nitrite salt other than sodium nitrite or organic solvents other than *n*-BuCl that are used. There is also no working example of a process in which no organic solvent is used. There is also no working example in which copper catalysts where at least 50 % but less than 100 % of the copper is in the copper (II) state is used.”

The Examiner alleges the specification does not enable the use of nitrite salts other than sodium nitrite. One skilled in the art appreciates that for diazotization reactions the critical component of the nitrite salt is the nitrite itself and not the counterion. Nitrite salts in the presence of HCl dissociate to both nitrous acid (HONO) and the chloride salt of the corresponding cation. The selection of the nitrite salt is discussed in paragraph [0117] on page 5, beginning at the 5th line below Scheme 1 of the specification as published (US2007/0161797A1):

“Various nitrite salts can be used, such as sodium nitrite, potassium nitrite, calcium nitrite, or any alkali or alkali earth nitrite. A suitable nitrite salt is sodium nitrite for the reasons of cost and availability”.

The counterion of the nitrite salt is not critical, and the use of any nitrite salt is therefore suitable for the present method.

The Examiner alleges the specification does not enable the use of any organic reaction solvents other than *n*-BuCl or the absence of an organic solvent. One skilled in the art recognizes the phrase “optionally in the presence of an organic solvent” in claim 1 does not mean “absence of solvent”. Diazotization and subsequent decomposition reactions are generally conducted using aqueous solutions. The optional organic solvent forms a separate organic phase to extract the product. Accordingly the presence or absence of an organic solvent in the present process is not critical for the reaction. The specification explains in paragraph [0119] on page 5 of the specification as published (US2007/0161797A1) that the reaction can be run in aqueous HCl alone (i.e. a one-phase system). Generating a diazonium salt in aqueous HCl in the absence of organic solvent is well documented in the literature. The three references listed in paragraph [0117] on page 5, beginning at the 8th line under Scheme 1 of the specification as published (US2007/0161797A1) disclose examples where diazonium salts and subsequent decomposition of these salts are performed in the absence of

an organic solvent. As described in the specification at paragraph [0120] on page 5, the present method can also be run in a two-phase system with an organic solvent forming the second phase:

“The decomposition can also be conducted in a two-phase system, comprising a suitable organic solvent and the aqueous solution of the one-phase system. The suitable organic solvent for the two-phase system can be, for example but not limitation, tetrahydrofuran, cyclohexane, ethyl acetate, *n*-chlorobutane, toluene, or benzene.”

A suitable solvent is easily identified by one skilled in the art on the basis of cost, availability, reactivity and immiscibility with the aqueous phase (i.e. an inexpensive, widely available solvent that forms a biphasic with water and will not react with a strong acid or diazonium salt). For Examples 1 and 5 described in paragraphs [0130] and [0135] on pages 7 and 8-9 of the specification as published (US2007/0161797A1), *n*-BuCl was selected as the organic solvent in a two-phase system. The specification therefore provides sufficient description to enable one skilled in the art to practice the present method in either the presence or absence of an organic solvent.

The Examiner alleges the specification does not enable the use of copper catalysts where at least 50 % but less than 100 % of the copper is in the copper(II) oxidation state. Diazotization and decomposition reactions have been reported for over a century, and general conditions to perform them are also well known. Therefore the present specification’s teaching of nitrite salts, solvents and reaction conditions should be regarded as more than sufficient for enablement. The present invention comes from the surprising discovery that copper(II) works particularly well for catalyzing the formation of 2,3-dichloropyridine 1. The Examples illustrate excellent results when about 100 % of the copper is in the copper(II) oxidation state. While based on this discovery copper(II) is reasonably predicted to provide good results in lower concentration (in proportion to its concentration), to achieve significant benefit a substantial percentage of the copper should be in the copper(II) oxidation state. Applicant has reasonably selected about 50% as the lower limit for the present claims. The present specification describes in paragraph [0118] on page 5 of the specification as published (US2007/0161797A1) a variety of copper catalysts meeting this requirement. This teaching is sufficient to allow one skilled in the art to select copper catalysts for the present method to the full extent claimed.

Regarding factor g) the Examiner states: “There is no evidence that the claimed process can produce high yield and highly pure products with any nitrite salt or any organic

solvent or with any copper catalyst wherein at least about 50 % of the copper is the copper (II) oxidation state”.

Demonstration of high yield and high purity from all possible reaction conditions is not required for an enabling disclosure. The present specification teaches the selection of nitrite salt, solvent and copper catalyst commensurate with what is necessary for preparing 2,3-dichloropyridine 1. Applicant has taught how to conduct the present method over a variety of conditions embraced by the claims. This is all that is required for enablement.

Regarding factor h) the Examiner quotes the breadth of the claims as a factor for rejecting claims 1 – 27. The Examiner states (in effect) that “...preparing 2,3-dichloropyridine using any nitrite salt or optionally any organic solvent in the presence of any copper catalyst wherein at least 50 % of the copper is in the copper II oxidation state [*exceeds the breadth of the disclosure?*]”.

The breadth of the claims is fully supported by the specification about how to make and use the process. As in the response to factors c) and g) above, the claims clearly enable one skilled in the art to use any nitrite salt, any organic solvent, and any copper catalyst wherein at least about 50 % of the copper is the copper(II) oxidation state in the claimed process.

Accordingly, Applicant respectfully maintains that Claims 1-27 fully meet all the requirements of 35 U.S.C. 112, first paragraph, and respectfully requests that the rejection be withdrawn. In view of the foregoing, allowance of the above-referenced application is respectfully requested.

Respectfully submitted,

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Dated: July 8, 2008